K093183

UNISENSE® FERTILITECH

510(k) Summary

JAN 11 2011

Administrative information:

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Date of summary: 05-January-2011

Device name:

Trade name	Common name	Device	Class	CFR Reference	Procode
EmbryoScope™ (Version D)	IVF Incubator	Assisted reproduction accessories	II	884.6120	85 MQG
EmbryoSlide™ (FT-S-ES-D)	IVF incubator accessory	Assisted reproduction labware	II	884.6160	85 MQK

EmbryoScope™ – (Version D):

Indication for Use: To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to three days (72 hr) covering the time from post-fertilization to day 3 of development.

Device Description:

The EmbryoScope™ – (Version D) is an embryo incubator, which performs a series of unattended measurements including time-lapse microscopy at multiple planes and logging of incubation conditions on individual embryos during their development. The device has a build-in microscope within a red light source. Separate processing units control the incubation environment and the data acquisition to ensure safe and reliable operation. The Device allows incubation of up to 72 individual embryos in six sterile disposable EmbryoSlides™ each with capacity for 12 embryos.

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EmbryoSlide™ (FT-S-ES-D):

Indication for Use: Preparing, storing, and transferring human embryos. To be used only with the EmbryoScope device.

Device Description:
The EmbryoSlide™ (FT-S-ES-D) is designed to fit the EmbryoScope™ – (Version D) incubator arm in order to control temperature. The EmbryoSlides are made of polystyrene, E-beam sterilized (SAL of 10^{-6}) and tested according to the ISO 11137 standard and relevant bioassays are performed. The slides are tested non-pyrogenic by Limulus Amebocyte Lysate (LAL), have passed the cytotoxicity test and are non-embryotoxic as tested by the mouse embryo assay (MEA).

Comparison to Predicate Device:

The Cook Mini-Incubator is the device identified by Unisense FertiliTech A/S for the substantial equivalence comparison .This is based on the fact that both incubators use direct heating which is considered as an important parameter according to intended use.

Table 1: Comparison of EmbryoScope™ - (Version D) to COOK Mini-Incubator – K983642

	EmbryoScope™ (Version D)	**COOK Mini-Incubator K983642**
Indication for use	To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to three days (72 hr) covering the time from post-fertilization to day 3 of development.	The COOK Mini-Incubator is intended to be used to store and preserve gametes and/or embryos at or near body temperature.
Discussion of Non-Clinical Tests performed for Determination of Substantial Equivalence	Underwent and passed electrical safety electromagnetic compatibility, environmental and operating performance testing. Classification according to IEC 60601-1.	Subjected to electrical safety, electromagnetic compatibility acceptability and operating performance. The incubator passed all these tests.

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Table 2: Comparison of EmbryoSlide™ to Nunc IVF 4-well Dish.

	EmbryoSlide™	**Nunc IVF 4-Well Dish K070047**
Indication for use	Preparing, storing, and transferring human embryos. To be used only with the EmbryoScope device.	In vitro fertilization techniques, cell culture.
Contraindication	N/A	N/A
Patient / embryo contact material	Polystyrene surface	Polystyrene surface
Design features	The slide is optimised optically clear. The lid and slide have a marking which requires that the lid always has the same orientation; thus cross contamination can be minimized. The lid can be handled by one hand while other lab equipment can be handled by the other hand. The wells are numbered.	The bottom of the plate is optimised flat and optically clear. The lid and plate have a cut off corner which requires that the lid always has the same orientation; thus cross contamination can be minimized. The lid can be handled by one hand while other lab equipment can be handled by the other hand. The plates can be stacked.
Safety features	N/A	N/A
Other relevant characteristics	• Sterile (SAL 10^{-6}) • Tested non-pyrogenic by LAL • Passed 1-cell mouse embryo test (MEA)	• Sterile (SAL 10^{-6}) • Tested non-pyrogenic by LAL • Passed 1-cell mouse embryo test (MEA)

Summary of comparison to predicate devices:

The EmbryoScope™ – (Version D) and the COOK Mini-Incubator incubator are both incubators controlling the environment according to primarily gas and temperature. The devices enhance safety by continuously monitoring the critical functions. Both incubators use direct heating of the culture dish. This principle is shown to be very effective in order to control the temperature as "the direct heat transfer culture incubator has superior temperature maintenance compared to a large volume air convection incubator" in: Cooke et al., "Objective Assessments of Temperature Maintenance Using In Vitro Culture techniques". 2002, Journal of Assisted Reproduction and Genetics, Vol 19, p. 368-375.

The EmbryoScope™ – (version D) has a build in microscope. This feature is not an option in the predicate device but the light intensity is compared to conventional light microscopes used in the IVF clinic and the data shows that it is comparable and thus safe for the embryos and in addition the embryo disturbance is minimized as the EmbryoSlides stay in the controlled incubation environment during microscopy. The

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concept with a build-in microscope is not new but an option in workstations as "the Custom products IVF Workstation" from MidAtlantic Diagnostics, Inc – K991216. It should also be noted that microscopes for use in general assisted reproductive procedures are classified as Class I exempt products under 21 CFR 884.6190, Assisted Reproductive Microscopes and Microscope Accessories).

In the EmbryoScope™ – (Version D) the oxygen range (3-20%) can be controlled. The concept of controlling Oxygen levels in incubators is not new. Ex.: The Forma Scientific Incubator – K991408) allows for the direct control of oxygen levels (2-20%).

By using an oil overlay and a dedicated slide lid increased humidity is avoided in the EmbryoScope™ – (Version D) thus reducing the contamination risk. This is different from the Predicate Device.

The EmbryoSlides™ and the Nunc IVF 4-Well Dish have similar applications, which include cell culturing and IVF. Both devices are sterile (SAL of 10^{-6}), non-pyrogenic, and non-embryotoxic. They are made of the same material, polystyrene and are similar in configuration, with each well having optically clear surface. The design as such is different as each EmbryoSlide™ has 12 wells and other well dimensions, but the embryo survival rate is shown to be comparable to the Predicate Device.

Summary: The differences between the EmbryoScope™ – (Version D), EmbryoSlide™ and the Predicate Devices do not alter the safety and effectiveness of the device. The EmbryoScope™ – (Version D) and related accessory the EmbryoSlide™ are similar, with respect to the FDA published predicate device description.

Clinical Testing:

Clinical data showed that the EmbryoScope™ – (Version D) performs according to the intended use of the device. No significant difference was found between the rates of ongoing pregnancies in a standard incubator and the EmbryoScope™ – (Version D). No adverse effects of image acquisition were observed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Silver Spring, MD 20993-0002

Ms. Mette Munch
QA Manager
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JAN 11 2011

Re: K092183
Trade Name: EmbryoScope™ (Version D)
EmbryoSlide™
Regulation Number: 21 CFR §884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: MQG, MQK, MTX
Dated: January 5, 2011
Received: January 7, 2011

Dear Ms. Munch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JAN 1 1 2011

Indications for Use Form

510(k) Number (if known): K092183

Device Name: EmbryoScope™ - (Version D)

Indications for Use:

To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to three days (72 hr) covering the time from post-fertilization to day 3 of development.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) _____

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K092183

Indications for Use Form

JAN 1 1 2011

510(k) Number (if known): K092183

Device Name: EmbryoSlide™

Indications for Use:

Preparing, storing, and transferring human embryos. To be used only with the EmbryoScope device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) _____

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K092183